

Complaint

IN THE MATTER OF

JOHNSON & JOHNSON

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE
COMMISSION ACT*Docket C-4154; File No. 0510050**Complaint, December 21, 2005--Decision, December 21, 2005*

This consent order addresses the acquisition by Respondent Johnson & Johnson -- a comprehensive and broadly-based manufacturer of products related to all aspects of human health care -- of Guidant Corporation, which manufactures products in three broad business units: cardiac rhythm management, vascular intervention, and cardiac surgery. The order, among other things, requires the respondent to grant to Abbott Laboratories or another Commission-approved firm -- within ten days and at no minimum price -- a fully paid-up, non-exclusive, irrevocable license that permits the licensee to make and sell drug-eluting stents with a drug delivery system, which are used to treat coronary artery disease by propping open a clogged artery and eluting a drug, thereby helping to prevent renarrowing of the artery. The consent order also requires the respondent to divest to Datascope or another Commission-approved firm, within fifteen days, its endoscopic vessel harvesting product line, which is used in coronary artery bypass graft surgery to remove a patient's leg vein, arm artery, or other blood vessel; that vessel is then used as a conduit to bypass one or more blocked coronary arteries. In addition, the consent order requires the respondent to terminate its agreement to distribute the proximal anastomotic assist device -- used to avoid the need to clamp the aorta when attaching a harvested vessel to it -- of Novare Surgical System, Inc.

Participants

For the Commission: *Jonathan S. Klarfield, Jeffrey H. Perry, Kari A. Wallace, Brendan J. McNamara, Tammy L. Imhoff, Thomas D. Mays, Kenneth A. Libby, Sylvia M. Brooks, Katherine L. Rosenberg, Michael R. Moiseyev, Daniel P. Ducore, Elizabeth A. Schneirov, Michael G. Vita and Mark Frankena.*

For the Respondent: *Steve Newborn, Weil, Gotshal & Manges, LLP.*

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COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Johnson & Johnson (“J&J”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Guidant Corporation (“Guidant”), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act (“FTC Act”), as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. DEFINITIONS

1. “Commission” means the Federal Trade Commission.
2. “J&J” or “Respondent” means Johnson & Johnson, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Johnson & Johnson, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
3. “Guidant” means Guidant Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Guidant Corporation, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
4. “Drug Eluting Stent” or “DES” means a stent that elutes or otherwise delivers one or more drugs or pharmaceutical compositions for the treatment of coronary artery disease.

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5. “Endoscopic Vessel Harvesting Device” or “EVH Device” means a medical device consisting of various components to allow for the minimally-invasive removal of the saphenous vein, the radial artery, or other conduit for use in coronary artery bypass graft surgery, from a patient’s body with the use of endoscopic technology and equipment.

6. “FDA” means the United States Food and Drug Administration.

7. “Proximal Anastomotic Assist Device” or “Proximal AAD” means a medical device used to create a bloodless field, without clamping the aorta, to assist in the creation of a proximal anastomosis as part of a coronary artery bypass graft surgery.

8. “Rapid Exchange,” “Rapid Exchange delivery system” or “RX” means intraluminal catheters and stent and embolic protection delivery systems having a guidewire lumen with a proximal guidewire port located substantially remote from the proximal end of the catheter shaft.

II. RESPONDENT

9. Respondent J&J is a corporation organized, existing, and doing business under and by virtue of the laws of the state of New Jersey, with its office and principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. J&J, among other things, is engaged in the research, development, marketing and sale of interventional cardiology products, including Drug Eluting Stents, and cardiac surgery devices, including Endoscopic Vessel Harvesting Devices and Proximal Anastomotic Assist Devices.

10. J&J is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affects commerce, as “commerce” is

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defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

III. ACQUIRED COMPANY

11. Guidant is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Indiana, with its office and principal place of business located at 111 Monument Circle, Indianapolis, Indiana 46204. Guidant, among other things, is engaged in the research, development, marketing, and sale of interventional cardiology products, including the research and development of Drug Eluting Stents, and cardiac surgery devices, including Endoscopic Vessel Harvesting Devices and Proximal Anastomotic Assist Devices.

12. Guidant is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affects commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

IV. PROPOSED ACQUISITION

13. On December 15, 2004, J&J and Guidant entered into an agreement and plan of merger (the “Purchase Agreement”) whereby J&J agreed to acquire Guidant in a transaction valued at approximately \$25.4 billion (the “Acquisition”).

V. RELEVANT MARKET

14. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the research, development, manufacture, and/or sale of the following products:

- a. Drug Eluting Stents;

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- b. Endoscopic Vessel Harvesting Devices; and
- c. Proximal Anastomotic Assist Devices.

15. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant lines of commerce.

VI. STRUCTURE OF THE MARKETS

16. J&J is one of only two companies (the other is Boston Scientific Corporation) currently selling DESs in the United States. At least three other companies, including Guidant, are involved in the research and development of DESs and are poised to receive FDA approval to sell DESs in the United States in the next two to three years.

17. There are only three companies free to offer Rapid Exchange versions of their DESs: J&J, Guidant and Boston Scientific. No other company has licenses or access to the Rapid Exchange patents. Currently, over 70 percent of the DES devices sold in the United States employ the Rapid Exchange delivery system, and the percentage of DES devices sold on Rapid Exchange delivery systems in the United States is expected to continue to increase rapidly.

18. Until recently, J&J and Guidant were the sole competitors in the market for EVH Devices. Although another company, Terumo Corporation, received FDA approval for its device in January of 2005, J&J and Guidant still dominate the market for these devices, and together account for almost 100 percent of sales in the U.S. market for EVH Devices.

19. The U.S. market for Proximal AADs is also highly concentrated as measured by the Herfindahl-Hirschman Index ("HHI"). J&J and Guidant are two of only three companies that compete in the market for Proximal AADs. Guidant is the market

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leader in this market, and together with J&J, accounts for over 95 percent of unit sales of Proximal AADs in the U.S. market.

VII. ENTRY CONDITIONS

20. Developing a Drug Eluting Stent, Endoscopic Vessel Harvesting Device, or Proximal Anastomotic Assist Device, working around and/or acquiring licenses to critical intellectual property related to those devices, obtaining FDA approval for those devices, and marketing those devices, takes significantly longer than two years. Therefore, entry into the relevant lines of commerce described in Paragraph 14 would not be timely, likely, or sufficient in magnitude, character and scope to deter or counteract the anti-competitive effects of the Acquisition.

VIII. EFFECTS OF THE ACQUISITION

21. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. eliminating potential competition between two of only three suppliers of Drug Eluting Stents with access to a Rapid Exchange delivery system;
- b. eliminating actual, direct and substantial competition between J&J and Guidant in the markets for the research, development, marketing, and sale of Endoscopic Vessel Harvesting Devices and Proximal Anastomotic Assist Devices;
- c. increasing the ability of the merged entity to unilaterally raise prices in the relevant markets; and
- d. reducing research and development in the relevant markets.

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IX. VIOLATIONS CHARGED

22. The Purchase Agreement described in Paragraph 13 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

23. The Acquisition described in Paragraph 13, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this 21st day of December, 2005, issues its Complaint against said Respondent.

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DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed acquisition by Respondent Johnson & Johnson (“J&J” or “Respondent”) of Guidant Corporation (“Guidant”), and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

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1. Respondent J&J is a corporation organized, existing and doing business under and by virtue of the laws of the State of New Jersey, with its offices and principal place of business located at One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

2. Guidant is a corporation organized, existing and doing business under and by virtue of the laws of the State of Indiana, with its offices and principal place of business located at 111 Monument Circle, Indianapolis, IN 46204.

3. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “J&J” or “Respondent” means Johnson & Johnson, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Johnson & Johnson, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Effective Date, the term “J&J” shall include Guidant.
- B. “Guidant” means Guidant Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Guidant Corporation, and the respective directors, officers,

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employees, agents, representatives, successors, and assigns of each.

- C. “Commission” means the Federal Trade Commission.
- D. “Abbott” means Abbott Laboratories, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Illinois, having its principal place of business located at 100 Abbott Park Road, Abbott Park, IL 60064.
- E. “Abbott Agreement” means the “License Agreement” by and between J&J and Abbott dated August 12, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Drug Eluting Stent Patents to be licensed, that have been approved by the Commission to accomplish the requirements of this Order. The Abbott Agreement is attached to this Order as non-public Appendix I.
- F. “Abbott Combination Stent” means the first Stent product designated and commercialized by Abbott (or Abbott’s assignee of the entire Abbott Agreement) for the treatment of coronary artery disease that includes ABT-578 in combination with one of the agents identified in non-public Appendix II.
- G. “Abbott Drug Eluting Stent” means a Stent that elutes or otherwise delivers ABT-578 alone for the treatment of coronary artery disease.
- H. “ABT-578” means the agent disclosed in U.S. Patent Nos. 6015815, 6329386, 5527907, 5583139 and 5672605, which is the active drug agent

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Abbott is currently using in its clinical trial of the ZoMaxx™ stent.

- I. “Acquisition” means the acquisition contemplated by the “Agreement and Plan of Merger” dated as of December 15, 2004, by and among J&J and Guidant (“Acquisition Agreement”), whereby J&J agreed to acquire Guidant.
- J. “Actual Cost” means the cost of direct labor and direct material used to provide the relevant assistance or service, plus an allocation of overhead that is in the same proportion that was used by the Respondent on July 2, 2005.
- K. “Additional Drug Eluting Stent Patents” means all U.S. and foreign Patents of Respondent listed in Appendix III.
- L. “Agency(ies)” means any governmental regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s) or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution or sale of Drug Eluting Stents or EVH Products.
- M. “Anastomotic Assist Distribution Agreement” means the September 12, 2003, Distribution Agreement by and between Ethicon, Inc., a subsidiary of Respondent, and Novare, as amended by letter dated November 30, 2004.
- N. “Business Day(s)” means any day other than a Saturday, Sunday, or federal holiday.
- O. “Closing Date” means the date on which Respondent (or a Divestiture Trustee) and a

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Commission-approved Acquirer consummate a transaction to grant, license, deliver or otherwise convey relevant assets pursuant to this Order.

P. “Commission-approved Acquirer” means the following:

1. as to the Drug Eluting Stent Patents, Abbott, if Abbott has not been rejected by the Commission pursuant to Paragraph II.A. of this Order;
2. as to the EVH Business, Datascope, if Datascope has not been rejected by the Commission pursuant to Paragraph III.A. of this Order; or
3. an entity that receives the prior approval of the Commission to receive particular assets that the Respondent is required to grant, license, deliver or otherwise convey pursuant to this Order.

Q. “Confidential Business Information” means all information owned by, or in the possession or control of, Respondent that is not in the public domain and that is related to the research, Development, manufacture, marketing, importation, exportation, supply, sales, sales support, or use of a Product; *provided, however*, that “Confidential Business Information” shall not include (1) information that subsequently falls within the public domain through no violation of this Order or of any confidentiality agreement with respect to such information by Respondent or (2) information that Guidant can demonstrate it obtained without the assistance of Respondent prior to the Acquisition.

R. “Datascope” means Datascope Corp., a corporation organized, existing, and doing business under and

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by virtue of the laws of the State of Delaware, having its principal place of business located at 14 Philips Parkway, Montvale, NJ 08933.

- S. “Datascope Agreement” means the “Purchase Agreement” by and between Ethicon, Inc., a subsidiary of J&J, and Datascope dated as of September 27, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the EVH Business, that have been approved by the Commission to accomplish the requirements of this Order. The Datascope Agreement is attached to this Order as non-public Appendix IV.
- T. “Designee” means any entity that will manufacture a J&J EVH Product or a Licensed EVH Product for a Commission-approved Acquirer.
- U. “Development” means all preclinical and clinical drug and/or device development activities, including test method development and stability testing, toxicology, bioequivalency, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing and sale of a Product (including any governmental price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.

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- V. “Divestiture Trustee” means a trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- W. “Drug Eluting Stent” means a Stent that elutes or otherwise delivers one or more drugs or pharmaceutical compositions for the treatment of coronary artery disease.
- X. “Drug Eluting Stent Patents” means all U.S. and foreign Patents of Respondent, other than Excluded Drug Eluting Stent Patents, that claim (1) drugs, pharmaceutical compositions, coatings or polymers used on Stents or otherwise in combination with Stents; (2) methods of manufacture, use or sale of Stents including, bearing, or otherwise in combination with such drugs, pharmaceutical compositions, coatings and/or polymers; (3) products or systems for the intravascular delivery of such Stents; and/or (4) intraluminal catheters, Stent delivery systems and embolic protection delivery systems (but not the design of Stents or embolic protection devices per se) having a guidewire lumen with a proximal guidewire port located substantially remote from the proximal end of the catheter shaft.
- Y. “Effective Date” means the earlier of the following dates:
 - 1. the date the Respondent closes on the Acquisition Agreement; or
 - 2. the date the merger contemplated by the Acquisition Agreement becomes effective by filing articles of merger with the Secretary of State of the State of Indiana.

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- Z. “EVH Business” means all of Respondent’s assets, tangible and intangible, businesses and goodwill, related to the research, Development, manufacture, distribution, marketing or sale of J&J EVH Products, including, without limitation, the following:
1. all EVH Intellectual Property;
 2. all EVH Manufacturing Technology;
 3. all EVH Scientific and Regulatory Material;
 4. all books, records and files related to the foregoing or to J&J EVH Products;
 5. all EVH Manufacturing Equipment;
 6. to the extent related to the J&J EVH Products, all of Respondent’s rights, titles and interests in and to the contracts entered into in the ordinary course of business with customers, suppliers, sales representatives, distributors, agents, personal property lessors, personal property lessees, licensors, licensees, consignors, and consignees, in each case that are Third Parties, including, without limitation, all of Respondent contracts with any Third Party to the extent related to the supply of components used in the manufacture of J&J EVH Products;
 7. all inventory, including raw materials, packaging materials, work-in-process and finished goods, in each case to the extent consisting of, or intended for use in the manufacture of, J&J EVH Products;
 8. all commitments and orders for the purchase of goods that have not been shipped, to the extent such goods are, or

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are intended for use in the manufacture of, J&J EVH Products;

9. all rights under warranties and guarantees, express or implied, with respect to J&J EVH Products; and
10. all items of prepaid expenses, to the extent related to J&J EVH Products;

provided, however, that “EVH Business” does not include any portion of any of the foregoing assets, businesses and goodwill that does not relate to J&J EVH Products;

provided further, however, that “EVH Business” does not include any of the following: (a) (i) the name “Johnson & Johnson”, “Ethicon”, “CardioVations”, or the names of any other divisions, businesses, corporations or companies owned by Respondent or (ii) any trademarks, trade names or logos used on other of Respondent’s Products; (b) any interest in real property; (c) any plant or other facilities; (d) any personal property; (e) any equipment or contracts for the sterilization, labeling or packaging of any Products; or (f) any assets, tangible and intangible, businesses or goodwill that were owned by Guidant immediately prior to the Effective Date;

provided further, however, that with respect to documents or other materials included in the EVH Business that contain information (a) that relates both to the J&J EVH Products and to other products or businesses of Respondent or (b) for which Respondent has a legal obligation to retain the original copies, Respondent shall be required to provide only copies or, at its option, relevant excerpts of such documents and materials, but Respondent shall provide the Commission-approved Acquirer access to the originals of such documents as necessary, it being a purpose of this proviso to ensure that Respondent not be required to divest itself completely of

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records or information that relates to products or businesses other than the J&J EVH Products;

provided further, however, that with respect to any contract or agreement included in the EVH Business that relates both to the J&J EVH Products and to any other product, Respondent may, concurrently with assigning such contract or agreement to the extent it relates to the J&J EVH Products, retain its rights under such contract or agreement for purposes of such other product(s).

AA. “EVH Employee Information” means the following, as and to the extent permitted by Law:

1. with respect to each EVH Employee, the following information:
 - a. the date of hire and effective service date;
 - b. job title or position held;
 - c. a specific description of the employee’s responsibilities related to the EVH Business;
 - d. for sales representatives, the sales ranking as of September 30, 2005, and for other employees, the most recent performance rating;
 - e. the base salary range of all EVH Employees having the same title or position;
 - f. the aggregate annual compensation for the Respondent’s last fiscal year and as targeted for the current fiscal year;
 - g. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and

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- h. any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees.
 - 2. at the Commission-approved Acquirer's option, copies of all employee benefit plans and summary plan descriptions (if any) applicable to the EVH Employees.
- BB. "EVH Employees" means all those employees listed in non-public Appendix V to this Decision and Order.
- CC. "EVH Intellectual Property" means all of the following that are owned by Respondent, to the extent related to the J&J EVH Products:
- 1. Patents;
 - 2. trademarks, trade names, trade dress, trade secrets, know-how, techniques, data, inventions, practices, methods and other confidential or proprietary technical, business, research, Development and other information;
 - 3. rights to obtain and file for Patents and registrations thereof; and
 - 4. rights under any license to any of the foregoing;
- provided, however*, "EVH Intellectual Property" does not include (i) the name "Johnson & Johnson", "Ethicon", "CardioVations", or the names of any other corporations, divisions or companies owned by Respondent or (ii) any trademarks, trade names or logos used on other of Respondent's Products.
- DD. "EVH Kits" means procedural kits for endoscopic vessel harvesting, including those currently marketed by

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Respondent under the trademarks CLEARGLIDE® or WATCHBAND INCISION™.

- EE. “EVH Manufacturing Equipment” means all equipment of Respondent utilized in the manufacture of J&J EVH Products, but does not include (i) any sterilization, labeling or packaging equipment or (ii) any assets utilized by Guidant in the manufacture of EVH Products immediately prior to the Effective Date.
- FF. “EVH Manufacturing Technology” means all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture (including that relating to all equipment used to manufacture a J&J EVH Product in final finished form), validation, packaging, release testing, stability and shelf life of J&J EVH Products, including all product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering and other manuals and drawings, standard operating procedures, flow diagrams, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, safety, efficacy, bioequivalency, quality assurance, quality control and clinical data, research records, compositions, annual product reviews, process validation reports, analytical method validation reports, specifications for stability trending and process controls, testing and reference standards for impurities in and degradation of products, technical data packages, chemical and physical characterizations, dissolution test methods and results, formulations for administration, clinical trial reports, regulatory communications and labeling of, for or with respect to the J&J EVH Products, and all other information related to the manufacturing process, supplier lists, and supplier contracts for the J&J EVH Products.

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- GG. “EVH Products” means endoscopic vessel harvesting Products, whether or not included in EVH Kits, but shall not mean the EVH Kits themselves.
- HH. “EVH Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and clinical trial materials and information related to J&J EVH Products, and all of Respondent’s rights to use such materials, in any and all jurisdictions (to the extent Respondent can legally transfer such rights).
- II. “Excluded Drug Eluting Stent Patents” means (1) Patents owned or controlled by a Third Party that does not qualify as an affiliate of Respondent as of the Closing Date, except to the extent such Third Party Patent is licensed to Respondent at the Closing Date with the right to sublicense (a) without consent or (b) by mere notice to such Third Party, and (i) without any additional payment or other consideration (other than payments or other consideration, including royalty payments, which the Commission-approved Acquirer agrees to pay or provide) and (ii) without any other undertaking by Respondent that is not a de minimis undertaking; (2) Patents or Patent applications that pertain to the manufacture, use or sale of Rapamycin or any analog of Rapamycin, except to the extent, if any, such rights pertain to ABT-578; and (3) any Patents or Patent claims solely claiming balloon material for an intraluminal catheter or Stent delivery system.
- JJ. “Excluded EVH Products” means: (1) any and all devices marketed by Respondent as (a) the HARMONIC SCALPEL® or (b) the ALLPORT® Clip Applier; (2) any and all sutures, whether or not part of any ENDOLOOP® or other vessel ligator (including, but not limited to the sutures currently marketed by Respondent as the Ethibond Excel® sutures); (3) the metal “pigtail” dissector manufactured by Storz, purchased by Respondent from

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Storz, and sold by Respondent under the Storz name; (4) any endoscopes manufactured by Third Parties (including but not limited to Storz and Olympus) and previously marketed, sold or distributed by Respondent; (5) the DERMABOND® Topical Skin Adhesive; and (6) any EVH Products researched, Developed, manufactured or sold by Guidant immediately prior to the Effective Date.

KK. “Field” means the prevention, treatment, diagnosis, or control of a particular medical condition.

LL. “Governmental Entity” means any Federal, state, local or non-U.S. government or any court, legislature, governmental agency or governmental commission or any judicial or regulatory authority of any government.

MM. “Interim Monitor” means a monitor appointed by the Commission pursuant to Paragraph V of this Order.

NN. “J&J Anastomotic Assist Products” mean those anastomotic assist Products distributed and sold by J&J immediately prior to the Effective Date.

OO. “J&J EVH Products” mean those EVH Products, other than Excluded EVH Products or Licensed EVH Products, researched, Developed, manufactured and sold by J&J immediately prior to the Effective Date, and including all such EVH Products that are introduced by Respondent on or before the Closing Date.

PP. “Law” means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law by any Governmental Entity.

QQ. “Licensed EVH Products” means the following devices, the product code numbers for which are listed in non-public Appendix VI.: (1) the device currently marketed in EVH Kits by Respondent as the ENDOPATH® Vessel

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Scissors; (2) the atraumatic blunt dissector (sometimes referred to as the “cherry dissector” or “Kittner dissector”) that is currently marketed in EVH Kits by Respondent; and (3) the ENDOLOOP® One Tie Vessel Ligator that is currently marketed by Respondent in the Field of endoscopic vessel harvesting (but excluding any suture that is a component of any such vessel ligator).

- RR. “Novare” means Novare Surgical Systems, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, having its principal place of business located at 10231 Bubb Road, Cupertino, California 95014.
- SS. “Patents” means all patents, patent applications and statutory invention registrations in which Respondent holds rights, either through assignment or license, as of the Effective Date (except where this Order specifies a different time), and includes all reissues, divisions, continuations, continuations-in-part, to the extent the claims of such continuations-in-part are fully supported pursuant to 35 U.S.C. § 112 by such patents and/or applications owned or licensed by Respondent as of the Effective Date, substitutions, reexaminations, restorations, and/or patent term extensions thereof, all inventions disclosed therein, all rights therein provided by international treaties and conventions, and all rights to obtain and file for patents and registrations thereto, related to a Product.
- TT. “PC Coating” shall mean polymerized phosphorylcholine coating.
- UU. “Product” means any medical device or pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically or genetically active ingredient.

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VV. “Remedial Agreement” means the following:

1. the Abbott Agreement, if such agreement has not been rejected by the Commission pursuant to Paragraph II.A. of this Order;
2. the Datascope Agreement, if such agreement has not been rejected by the Commission pursuant to Paragraph III.A. of this Order; and
3. any agreement between Respondent and a Commission-approved Acquirer (or between a Divestiture Trustee and a Commission-approved Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets to be granted, licensed, delivered or otherwise conveyed, that have been approved by the Commission to accomplish the requirements of this Order.

WW. “Stent” means stents that provide intraluminal support through the use of metal members to form a stent scaffold, which is principally responsible for intraluminal support in the treatment of coronary artery disease. “Stent” excludes stents that are bioabsorbable or comprise scaffolds principally composed of non-metallic materials, such as ceramic.

XX. “Termination Agreement” means the “Termination and Release Agreement” by and between Ethicon, Inc., a subsidiary of J&J, and Novare dated September 28, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the J&J Anastomotic Assist Products, that have been approved by the Commission to accomplish the requirements of this Order. The Termination Agreement is attached to this Order as non-public Appendix VII.

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YY. “Third Party(ies)” means any private entity other than the following: (1) the Respondent, or (2) the Commission-approved Acquirer.

II.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Effective Date, Respondent shall grant an irrevocable, perpetual, fully paid-up and royalty-free non-exclusive license worldwide to the Drug Eluting Stent Patents to Abbott for the research, Development, manufacture, use, import, distribution, marketing or sale of Abbott Drug Eluting Stents and Abbott Combination Stents pursuant to and in accordance with the Abbott Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Abbott or to reduce any obligations of Respondent under such agreement);

provided, however, that, if Respondent has licensed the Drug Eluting Stent Patents to Abbott prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that Abbott is not an acceptable licensee of the Drug Eluting Stent Patents, then Respondent shall (1) grant an irrevocable, perpetual, fully paid-up and royalty-free non-exclusive license worldwide to the Drug Eluting Stent Patents and the Additional Drug Eluting Stent Patents (to the extent the Commission determines that the Commission-approved Acquirer requires access to the Drug Eluting Stent Patents and the Additional Drug Eluting Stent Patents in order to manufacture or sell Drug Eluting Stents without fear of infringement of any Patents of Respondent) within six (6) months from the date the Order becomes final, absolutely and in good faith, at no minimum price, to a Commission-approved Acquirer and only in a

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manner that receives the prior approval of the Commission; and (2) at Respondent's option, immediately rescind the transaction with Abbott;

provided further, however, that if Respondent has licensed the Drug Eluting Stent Patents to Abbott prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the Respondent that the manner in which the license was accomplished is not acceptable, the Commission may direct the Respondent, or appoint a Divestiture Trustee, pursuant to Paragraph VI of this Order, to effect such modifications to the manner of licensing the Drug Eluting Stent Patents to Abbott for the research, Development, manufacture, use, import, distribution, marketing or sale of Abbott Drug Eluting Stents and Abbott Combination Stents for the treatment of coronary artery disease (including, but not limited to, licensing the Additional Drug Eluting Stent Patents, and entering into additional agreements or arrangements) as may be necessary to satisfy the requirements of this Order;

provided further, however, that Respondent may include as part of a Remedial Agreement a requirement that the Commission-approved Acquirer make: (1) a one-time fixed payment upon FDA approval or first sale in the United States, whichever comes earlier, of a Drug Eluting Stent which practices under any Drug Eluting Stent Patents or Additional Drug Eluting Stent Patents; and (2) a one-time payment in the event that the Commission-approved Acquirer transfers the license;

provided further, however, that Respondent may include as part of a Remedial Agreement a requirement that the Commission-approved Acquirer pay royalties to the same extent and in the same amount that Respondent pays royalties to any Third Party. Such royalties shall be paid by the Commission-approved Acquirer directly to the Third Party and Respondent shall obtain no information about such payments except for an acknowledgment that the full payment has been made, and, if

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not, whether the underpayment was by more than five (5) percent;

provided further, however, that Respondent shall not be required to license to Abbott: (1) any Patents licensed under the June 2001 License Agreement between Abbott and Cordis Corporation; and (2) any portion of the Drug Eluting Stent Patents, or rights under those patents, if Abbott does not require such patent rights in order to sell Abbott Drug Eluting Stents or Abbott Combination Stents without fear of infringement of any Patents of Respondent.

- B. Any Remedial Agreement that has been approved by the Commission between Respondent (or a Divestiture Trustee) and a Commission-approved Acquirer of the Drug Eluting Stent Patents (and, if relevant, the Additional Drug Eluting Stent Patents) shall be deemed incorporated into this Order, and any failure by Respondent to comply with any term of such Remedial Agreement related to the Drug Eluting Stent Patents (and, if relevant, the Additional Drug Eluting Stent Patents) shall constitute a failure to comply with this Order.
- C. In the event that Respondent licenses the Drug Eluting Stent Patents to Abbott, Respondent shall include in the Remedial Agreement related to the Drug Eluting Stent Patents, and Respondent shall observe, a covenant that Respondent shall not join, or file, prosecute or maintain any suit, in Law or equity, against Abbott (or Abbott's assignee of the entire Abbott Agreement) for the research, Development, manufacture, use, import, distribution, marketing or sale of the Drug Eluting Stent Products currently being used in Abbott's ZoMaxx™ and ZoMaxx™ II clinical trials, and variations of concentrations of ABT-578, stent sizes, PC Coating, catheters and/or delivery systems (excluding their balloon materials) as Abbott (or such assignee) may choose to employ under any Patents licensed to Abbott under the Abbott Agreement.

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- D. In the event that Respondent licenses the Drug Eluting Stent Patents and the Additional Drug Eluting Stent Patents to a Commission-approved Acquirer other than Abbott pursuant to Section II.A of this Decision and Order, Respondent shall include in any Remedial Agreement related to the Drug Eluting Stent Patents and the Additional Drug Eluting Stent Patents, and Respondent shall observe, a covenant that Respondent shall not join, or file, prosecute or maintain any suit, in Law or equity, against the Commission-approved Acquirer (or the Commission-approved Acquirer's assignee of the entire Remedial Agreement) for the research, Development, manufacture, use, import, distribution, marketing or sale of Drug Eluting Stents identified in the Remedial Agreement under Drug Eluting Stent Patents or Additional Drug Eluting Stent Patents included in the Remedial Agreement with the Commission-approved Acquirer.
- E. Prior to the Closing Date, Respondent shall secure all consents and waivers from all Third Parties that are necessary for the licensing of the Drug Eluting Stent Patents (and, if relevant, the Additional Drug Eluting Stent Patents) to the Commission-approved Acquirer, or for the continued research, Development, manufacture, use, import, distribution, marketing or sale of Drug Eluting Stents by the Commission-approved Acquirer.
- F. If the Remedial Agreement does not license the Commission-approved Acquirer rights in and to any portion of the Additional Drug Eluting Stent Patents, then Respondent shall not seek to enjoin any transferee or acquirer of the Commission-approved Acquirer's rights to the Remedial Agreement in any action for infringement of any patent included within the Additional Drug Eluting Stent Patents; *provided, however*, that Respondent shall retain all its rights to seek past and future damages and other remedies provided for in the Patent Act (U.S.C. title 35).

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- G. The purpose of the grant, license, delivery and conveyance of the Drug Eluting Stent Patents (and, if relevant, the Additional Drug Eluting Stent Patents) to a Commission-approved Acquirer is to create an independent, viable and effective competitor in the Drug Eluting Stent market, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

III.

IT IS FURTHER ORDERED that:

- A. Not later than fifteen (15) Business Days after the Effective Date, Respondent shall divest the EVH Business to Datascope pursuant to and in accordance with the Datascope Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Datascope or to reduce any obligations of Respondent under such agreement);

provided, however, that, if Respondent has divested the EVH Business to Datascope prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that Datascope is not an acceptable acquirer of the EVH Business, then Respondent shall immediately rescind the transaction with Datascope and shall divest the EVH Business within six (6) months from the date the Order becomes final, absolutely and in good faith, at no minimum price, to a Commission-approved Acquirer and only in a manner that receives the prior approval of the Commission;

provided further, however, that if the Respondent has divested the EVH Business to Datascope prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the

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Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct the Respondent, or appoint a Divestiture Trustee, pursuant to Paragraph VI of this Order, to effect such modifications to the manner of divesting the EVH Business to Datascope (including, but not limited to, entering into additional agreements or arrangements) as may be necessary to satisfy the requirements of this Order;

provided further, however, that Respondent shall not be required to divest to the Commission-approved Acquirer any portion of the EVH Business if the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) does not require such portion of the EVH Business for the continued research, Development, manufacture, use, import, distribution, marketing or sale of the J&J EVH products.

- B. Any Remedial Agreement that has been approved by the Commission between Respondent (or a Divestiture Trustee) and a Commission-approved Acquirer of the EVH Business shall be deemed incorporated into this Order, and any failure by Respondent to comply with any term of such Remedial Agreement related to the EVH Business shall constitute a failure to comply with this Order.
- C. Until the Closing Date of the EVH Business, Respondent shall take such actions as are necessary to maintain the viability and marketability of the EVH Business and to prevent the destruction, removal, wasting, deterioration, or impairment of the EVH Business, except for ordinary wear and tear and the disposition of inventory and other assets in the ordinary course of business.
- D. At the option of the Commission-approved Acquirer (to be exercised no later than 30 days after the date the Commission-approved Acquirer signs a Remedial Agreement with Respondent to effect the acquisition of the

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EVH Business), Respondent shall include in any Remedial Agreement the following provisions, and Respondent shall commit to satisfy the following:

1. Respondent shall (a) grant an irrevocable, perpetual, fully paid-up and royalty free (except for pass-through royalties), non-exclusive license worldwide to Patents owned or exclusively licensed by Respondent and necessary to enable the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to research, Develop, manufacture, use, import, distribute, market and sell Licensed EVH Products in the Field of endoscopic vessel harvesting; and (b) in furtherance of the foregoing, provide the Commission-approved Acquirer with copies of the following documents, to the extent they are owned by, or in the possession, custody or control of, Respondent and related to the Licensed EVH Products: (i) design history files, technical files, drawings, product specifications, manufacturing process descriptions, validation documentation, packaging specifications, quality control standards and regulatory records, and (ii) specifications, drawings, manufacturing process descriptions and validation documentation for molds and other tooling used in manufacturing Licensed EVH Products; *provided, however*, that any portions of the documents described in this clause (b) that do not relate to the Licensed EVH Products or the J&J EVH Products may be excluded from such copies; *provided further, however*, that as regards to any documents described in this clause (b) that are not owned by Respondent and which Respondent is prohibited by contract or Law from providing to the Commission-approved Acquirer, Respondent shall not be required to provide such documents to the Commission-approved Acquirer if Respondent has made all reasonable efforts to obtain a waiver of such prohibition but has not been successful.

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2. Respondent shall, for a period of up to one (1) year after the Closing Date at no more than Respondent's Actual Cost, provide transition services necessary for the continued research, Development, manufacture, use, import, distribution, marketing or sale of J&J EVH Products and Licensed EVH Products by the Commission-approved Acquirer.
3. Respondent shall enter into an agreement to supply J&J EVH Products, Licensed EVH Products, HARMONIC SCALPEL® devices and ALLPORT® Clip Applicators to the Commission-approved Acquirer at no more than Respondent's Actual Cost for a period not longer than two (2) years following the Closing Date; *provided, however,* that Respondent may, for the term of any such supply agreement, postpone the assignment of any contract that is needed by Respondent to meet its obligations under such supply agreement.
4. Respondent shall provide to the Commission-approved Acquirer all documents or materials in Respondent's possession, custody or control as of the Effective Date to the extent related to Third Party EVH Products or EVH Products sold by Guidant prior to the Effective Date; *provided, however,* that as regards to any documents or materials described in this Paragraph III.D.4. that are not owned by Respondent and which Respondent is prohibited by contract or Law from providing to the Commission-approved Acquirer, Respondent shall not be required to provide such documents or materials to the Commission-approved Acquirer if Respondent has made all reasonable efforts to obtain a waiver of such prohibition but has not been successful; *provided further, however,* that Respondent shall not be required to provide to the Commission-approved Acquirer any documents or materials described in this Paragraph III.D.4. that were owned by, or in the possession, custody or control of, Guidant immediately prior to the Effective Date.

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E. Respondent shall:

1. not later than fifteen (15) days after signing the Remedial Agreement, (a) provide to the Commission-approved Acquirer a list of all EVH Employees; (b) allow the Commission-approved Acquirer to interview any EVH Employees; and (c) in compliance with all Laws, allow the Commission-approved Acquirer to inspect the EVH Employee Information;
2. not later than fifteen (15) days after signing the Remedial Agreement, provide an opportunity for the Commission-approved Acquirer: (a) to meet personally, and outside the presence or hearing of any employee or agent of Respondent, with any one or more of the EVH Employees; and (b) to make offers of employment to any one or more of the EVH Employees; *provided, however*, that the Respondent may include in any Remedial Agreement related to the EVH Business a requirement that the Commission-approved Acquirer may not make offers of employment to more than three of the sales representatives listed on non-public Appendix V. for each of the Northeast and Southeast regions, or to more than one of the sales representatives listed on non-public Appendix V. for each of the Midwest and West regions; *provided further, however*, that the Commission-approved Acquirer shall be permitted to make an offer of employment to one additional sales representative within a region for each other sales representative within that region who has already declined an offer of employment;
3. not interfere, directly or indirectly, with the hiring or employing by the Commission-approved Acquirer of EVH Employees, and shall remove any impediments or incentives within the control of Respondent that may deter these employees from accepting employment with the Commission-approved Acquirer, including, but not limited to, any non-compete provisions of employment or

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other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by the Acquirer, and shall not make any counteroffer to an EVH Employee who receives a written offer of employment from the Commission-approved Acquirer; *provided, however*, that nothing in this Order shall be construed to require Respondent to terminate the employment of any employee or prevent Respondent from continuing the employment of any employee;

4. provide all EVH Employees with reasonable financial incentives to continue in their positions until the Closing Date. Such incentives shall include, but are not limited to, a continuation, until the Closing Date, of all employee benefits, including regularly scheduled raises, bonuses and vesting of pension benefits (as permitted by law and for those EVH Employees covered by a pension plan), offered by Respondent;
5. provide to each EVH Employee that is offered employment by the Commission-approved Acquirer financial incentives to accept employment with the Commission-approved Acquirer on or about the Closing Date, or reimburse the Commission-approved Acquirer for its provision of such incentive. Such incentives shall include a bonus for each such employee, equal to 15% of the sum of the employee's annual base salary and total commissions (if any) for the twelve (12) months prior to the date of the Remedial Agreement, who accepts an offer of employment from the Commission-approved Acquirer within one month of the Closing Date and remains employed by the Commission-approved Acquirer for a period of six (6) months, payable by Respondent in equal installments at three (3) months and six (6) months after the commencement of the employee's employment by the Commission-approved Acquirer; and

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6. not, for a period of one (1) year following the Closing Date, directly or indirectly, solicit or otherwise attempt to induce any of the EVH Employees to terminate their employment with the Commission-approved Acquirer; *provided however*, that Respondent may:

- a. advertise for employees in newspapers, trade publications or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at the EVH Employees, or
- b. hire EVH Employees who apply for employment with Respondent, as long as such employees were not solicited by Respondent in violation of this Paragraph III.E.6;

provided further however, that this Paragraph III.E.6 shall not prohibit Respondent from making offers of employment to or employing any EVH Employee after the thirtieth day following the date of the Remedial Agreement, or where the Commission-approved Acquirer has notified Respondent in writing that the Commission-approved Acquirer does not intend to make an offer of employment to that employee, or where such an offer has been made and the employee has declined the offer.

F. Prior to the Closing Date, Respondent shall secure all consents and waivers from all Third Parties that are necessary for the divestiture of the EVH Business, and for the continued research, Development, manufacture, use, import, distribution, marketing or sale of J&J EVH Products by the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer); *provided, however*, that Respondent shall not be required to obtain consents from customers necessary to divest contracts that, in the aggregate, represent less than 5% of Respondent's

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worldwide EVH Kit sales for the period January 1, 2005 to June 30, 2005.

- G. In the event that Respondent is unable to satisfy all conditions necessary to divest any intangible asset that is a permit, license or right granted by any domestic or foreign governmental entity, Respondent shall provide such assistance as the Commission-approved Acquirer may reasonably request in the Commission-approved Acquirer's efforts to obtain a comparable permit, license or right.
- H. Other than as necessary to comply with the requirements of this Order, Respondent shall not use, directly or indirectly, any Confidential Business Information related to the research, Development, manufacture, use, import, distribution, marketing or sale of the J&J EVH Products, and shall not disclose or convey such Confidential Business Information, directly or indirectly, to any person except in connection with the divestiture of the EVH Business, and to the Divestiture Trustee, if any; *provided however*, that Respondent may continue using, outside the Field of endoscopic vessel harvesting, such Confidential Business Information as it currently uses in connection with any of the Licensed EVH Products or Excluded EVH Products.
- I. Respondent shall, to the extent permissible under applicable laws and as a condition of continued employment post-divestiture, require that each employee of Respondent with access to Confidential Business Information related to the EVH Business sign a confidentiality agreement pursuant to which such employee shall be required to maintain all such Confidential Business Information strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order); *provided however*, that:

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1. Respondent may use such information only to the extent necessary to defend or prosecute claims relating to assets or liabilities that are retained by Respondent after divestiture;
 2. Respondent may also continue to use, and to share with employees of Respondent having a need to know same, such Confidential Business Information as they currently use in connection with any of the Licensed EVH Products or Excluded EVH Products outside the Field of endoscopic vessel harvesting; and
 3. This Paragraph III.I. shall not apply to any Confidential Business Information related to the EVH Business that Respondent can demonstrate to the Commission that Guidant had prior to the Effective Date.
- J. Counsel for Respondent (including in-house counsel under appropriate confidentiality arrangements) may retain unredacted copies of all documents or other materials provided to the Commission-approved Acquirer and may have access to original documents provided to the Commission-approved Acquirer. Respondent's use or disclosure of any documents or materials that are retained or accessed by Respondent solely by virtue of this Paragraph III.J (and not, for example, pursuant to the third proviso of Paragraph I.Z) shall be limited to the following:
1. to comply with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals), any data retention requirement of any applicable Governmental Entity, or any taxation requirements;
 2. to defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the EVH Business;

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provided, however, that Respondent shall: (1) require those (other than Governmental Entities) who view any documents or materials that are retained or accessed by Respondent solely by virtue of this Paragraph III.J. to enter into reasonable and customary confidentiality agreements with the Commission-approved Acquirer (but shall not be deemed to have violated this requirement if the Commission-approved Acquirer withholds such agreement unreasonably); (2) inform any Governmental Entities who seek to view any documents or materials that are retained or accessed by Respondent solely by virtue of this Paragraph III.J. of Respondent's obligation to keep such information confidential, and give the Commission-approved Acquirer as much prior notice of complying with such request from the Governmental Entity as is reasonable in the circumstances, subject to any requirements of Law; and (3) use all reasonable efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

- K. The purpose of the divestiture of the EVH Business is to ensure the continuing, viable, and competitive operation of the EVH Business in the same business and in the same manner in which the EVH Business was engaged at the time of the announcement of the proposed Acquisition and to remedy the lessening of competition alleged in the Commission's complaint.

IV.

IT IS FURTHER ORDERED that:

- A. Not later than ten (10) days after the Effective Date, Respondent shall terminate the Anastomotic Assist Distribution Agreement with Novare pursuant to and in accordance with the Termination Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to

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reduce any rights or benefits of Novare or to reduce any obligations of Respondent under such agreement).

- B. The Termination Agreement shall be deemed incorporated into this Order, and any failure by Respondent to comply with any term of such Termination Agreement shall constitute a failure to comply with this Order.
- C. Other than as necessary to comply with the requirements of this Order, for such period of time as provided in the Anastomotic Assist Distribution Agreement, Respondent shall not use, directly or indirectly, any Confidential Business Information related to the research, Development, manufacture, use, import, distribution, marketing or sale of the J&J Anastomotic Assist Products, and shall not disclose or convey such Confidential Business Information, directly or indirectly, to any person except in connection with the termination of the Anastomotic Assist Distribution Agreement, and to the Divestiture Trustee, if any; *provided however*, that any Confidential Business Information related to J&J Anastomotic Assist Products that are the subject of a recall or other corrective action may be disclosed to those persons having a need to know such information for the purpose of carrying out such corrective action; *provided further, however*, that Respondent may continue using, in connection with products other than anastomotic assist Products, such Confidential Business Information related to J&J Anastomotic Assist Products as it (a) developed or obtained from sources other than Novare, and (b) currently uses in connection with products other than anastomotic assist Products.
- D. The purpose of the termination of the Anastomotic Assist Distribution Agreement is to ensure the continuing, viable, and competitive marketing, distribution and sale of the J&J Anastomotic Assist Products to the same extent in which the J&J Anastomotic Assist Products were marketed, distributed and sold at the time of the

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announcement of the proposed Acquisition and to remedy the lessening of competition alleged in the Commission's complaint.

V.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondent expeditiously complies with all of its obligations and perform all of its responsibilities as required by Paragraph III of this Order and the Remedial Agreement related to the divestiture of the EVH Business.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent's compliance with the relevant requirements of this Order in a manner consistent with the purposes of this Order.
- D. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding

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the powers, duties, authorities, and responsibilities of the Interim Monitor:

1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of this Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of this Order and in consultation with the Commission.
2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
3. The Interim Monitor shall serve until the later of:
 - a. the completion by Respondent of the divestiture of all relevant assets required to be granted, licensed, delivered, or otherwise conveyed pursuant to this Order in a manner that fully satisfies the requirements of this Order and notification by the Commission-approved Acquirer to the Interim Monitor that it (or its Designee(s)) is fully capable of producing the J&J EVH Products acquired pursuant to a Remedial Agreement independently of Respondent; or
 - b. the completion by Respondent of the last obligation under this Order pertaining to the Interim Monitor's service;

provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of this Order.

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to

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Respondent's personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under this Order, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with this Order.

5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of the Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
6. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
7. Respondent shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the

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Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Commission-approved Acquirer with respect to the performance of Respondent's obligations under this Order or the Remedial Agreement. Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under this Order.

8. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
- G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.
- H. The Interim Monitor appointed pursuant to this Order may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

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VI.**IT IS FURTHER ORDERED** that:

- A. If Respondent has not fully complied with the obligations to grant, license, deliver or otherwise convey relevant assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to grant, license, deliver or otherwise convey the assets required to be granted, licensed, delivered or otherwise conveyed pursuant to each of the relevant Paragraphs in a manner that satisfies the requirements of each such Paragraph. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*I*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*I*), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to grant, license, deliver or otherwise convey the relevant assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(*I*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent

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shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
 - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to grant, license, deliver or otherwise convey the assets that are required by this Order to be granted, licensed, delivered or otherwise conveyed.
 - 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed Divestiture Trustee, by the court; *provided, however*, the Commission may extend the divestiture period only two (2) times.
 - 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities

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related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. Each divestiture shall be made in the manner and to an acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondent from among those approved by the Commission; *provided further, however*, that Respondent shall select such entity within five (5) Days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants,

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attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be granted, licensed, transferred, delivered or otherwise conveyed by this Order.
8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

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9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.
- G. The Divestiture Trustee appointed pursuant to this Paragraph may be the same person appointed as Interim Monitor pursuant to the relevant provisions of this Order.

VII.**IT IS FURTHER ORDERED** that:

- H. Within five (5) days of the Acquisition, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- I. Within thirty (30) days after the date this Order becomes final, and every sixty (60) Days thereafter until Respondent have fully complied with Paragraphs II.A., II.E., III.A., III.C., III.D., III.E., III.F., III.G., IV.A., and all its responsibilities to render transitional services to the Commission-approved Acquirer as provided in the Remedial Agreement(s), Respondent shall submit to the Commission a verified written report setting forth in detail

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the manner and form in which it intends to comply, is complying, and have complied with this Order. Respondent shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondent shall include in its reports, among other things that are required from time to time:

1. a full description of the efforts being made to comply with the relevant Paragraphs of this Order;
2. if Abbott is rejected by the Commission pursuant to Paragraph II.A., a description of all substantive contacts or negotiations related to the licensing of the Drug Eluting Stent Patents and the identity of all parties contacted and copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning completing its obligations to license the Drug Eluting Stent Patents;
3. if Datascope is rejected by the Commission pursuant to Paragraph III.A., a description of all substantive contacts or negotiations related to the divestiture of the EVH Business and the identity of all parties contacted and copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning completing its obligations to divest the EVH Business;
4. a detailed plan to deliver all Confidential Business Information required to be delivered to the Commission-approved Acquirer pursuant to Paragraphs III.A. and III.D., and agreed upon by the Commission-approved Acquirer and the Interim Monitor (if applicable) and any updates or changes to such plan;
5. a description of all Confidential Business Information delivered to the Commission-approved Acquirer,

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including the type of information delivered, method of delivery, and date(s) of delivery;

6. a description of the Confidential Business Information currently remaining to be delivered and a projected date(s) of delivery; and
7. a description of all technical assistance provided to the Commission-approved Acquirer during the reporting period.

VII.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of the Respondent, (2) acquisition, merger or consolidation of Respondent, or (3) any other change in the Respondent that may affect compliance obligations arising out of this Order, including, but not limited to, assignment, the creation or dissolution of subsidiaries, or any other change in Respondent.

VII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondent made to its principal United States offices, Respondent shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondent related to compliance with this Order; and

Decision and Order

- B. Upon five (5) days' notice to Respondent and without restraint or interference from Respondent, to interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

VIII.

IT IS FURTHER ORDERED that this Order shall terminate ten (10) years from the date on which this Order becomes final.

Decision and Order

**APPENDIX I
NON-PUBLIC**

ABBOTT AGREEMENT

**[Redacted From the Public Record Version But Incorporated
By Reference]**

**APPENDIX II
NON-PUBLIC**

AGENTS USED IN COMBINATION WITH ABT-578

**[Redacted From the Public Record Version But Incorporated
By Reference]**

Decision and Order

APPENDIX III
PUBLIC

ADDITIONAL DRUG ELUTING STENT PATENTS

ISSUED US PATENTS
5,421,955
5,514,154
5,569,295
5,603,721
5,649,952
5,728,158
5,735,893
5,766,238
5,916,234
6,056,776
6,066,167
6,066,168
6,309,412
6,432,133
6,485,511
6,511,504
6,596,022
6,620,193
6,626,933
6,629,991
6,689,159
6,908,479
B1 5,421,955
<u>Pending US Applications</u>
10/626,083
11/112,143

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**APPENDIX IV
NON-PUBLIC**

DATASCOPE AGREEMENT

**[Redacted From the Public Record Version But Incorporated
By Reference]**

**APPENDIX V
NON-PUBLIC**

EVH EMPLOYEES

**[Redacted From the Public Record Version But Incorporated
By Reference]**

**APPENDIX VI
NON-PUBLIC**

LICENSED PRODUCT CODE NUMBERS

**[Redacted From the Public Record Version But Incorporated
By Reference]**

**APPENDIX VII
NON-PUBLIC**

TERMINATION AGREEMENT

**[Redacted From the Public Record Version But Incorporated
By Reference]**

Analysis

**Analysis of Agreement Containing Consent Order to Aid
Public Comment**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Johnson & Johnson (“J&J”). The purpose of the proposed Consent Agreement is to remedy the anticompetitive effects that would otherwise result from J&J’s acquisition of Guidant Corporation (“Guidant”). Under the terms of the proposed Consent Agreement, J&J is required to (a) grant to a third party a fully paid-up, non-exclusive, irrevocable license, enabling that third party to make and sell drug-eluting stents (“DESS”) with the Rapid Exchange (“RX”) delivery system, (b) divest to a third party J&J’s endoscopic vessel harvesting (“EVH”) product line, and (c) terminate its agreement to distribute the proximal anastomotic assist device (“AAD”) of Novare Surgical System, Inc. (“Novare”).

The proposed Consent Agreement has been placed on the public record for thirty days to solicit comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement or make it final.

Pursuant to an Agreement and Plan of Merger dated December 15, 2004, J&J proposes to acquire Guidant in exchange for cash and voting securities in a transaction valued at approximately \$25.4 billion. The Commission’s complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by removing an imminent competitor from the U.S. market for DESS and by lessening competition in the U.S. markets for EVH devices and proximal AADs. The proposed Consent Agreement would remedy the alleged violations by replacing the competition that would be lost in these markets as a result of the acquisition.

Analysis

J&J is a comprehensive and broadly-based manufacturer of products related to all aspects of human health care. In 2004, J&J generated global sales of \$47.3 billion and U.S. sales of \$27.7 billion. J&J is divided into three business segments: Consumer, Pharmaceutical, and Medical Devices and Diagnostics. The products impacted by the proposed transaction, DESs, EVH devices, and proximal AADs, fall within J&J's Medical Devices and Diagnostics segment.

Guidant manufactures products in three broad business units: cardiac rhythm management, vascular intervention, and cardiac surgery. In 2004, Guidant's sales were \$3.8 billion globally and \$2.53 billion in the United States. Guidant's DES program is part of its vascular intervention business unit, and the company's EVH device and proximal AAD are part of the cardiac surgery business unit.

Drug -Eluting Stents

A DES is a medical device typically consisting of a thin, metallic stent coated with an antiproliferative drug and a polymer, mounted on a delivery system. Interventional cardiologists use DESs to treat coronary artery disease, a condition caused by the build up of plaque deposits within one or more coronary arteries leading to reduced blood flow. DESs work by propping open the clogged artery or arteries and eluting a drug, which helps prevent the renarrowing of the artery, called restenosis. DESs are the most effective minimally-invasive method for treating coronary artery disease, and other products and procedures are not economic substitutes for DESs.

DESs are sold mounted on a delivery system used to deploy the DES to the blocked area of the coronary artery. The two most common types of delivery system in the United States are over-the-wire and Rapid Exchange ("RX"). Over-the-wire delivery systems employ a long guidewire and require two operators to implant the DES. In contrast, the RX delivery system employs a shorter guidewire that can be handled by a single operator. RX

Analysis

delivery systems currently are highly preferred by physicians in the United States and are increasing in popularity. Boston Scientific Corporation and Guidant own the intellectual property rights to the RX delivery system in the United States. The companies have cross-licensed each other, and J&J has access to the RX delivery system through an agreement with Guidant. Both DESs currently on the market, J&J's Cypher® and Boston Scientific's Taxus®, are available on the RX delivery system.

The relevant geographic market in which to analyze the effects of the proposed acquisition on the DES market is the United States. DESs are medical devices that are regulated by the United States Food and Drug Administration ("FDA"). Performing the necessary clinical testing and navigating the approval process for the FDA can be burdensome and time-consuming. As such, DESs sold outside of the United States but not approved for sale in the United States do not provide viable competitive alternatives for U.S. consumers.

The U.S. market for DESs is highly concentrated; currently only two firms, J&J and Boston Scientific, have products on the market. Guidant's DES program is still in development, but it is anticipated to be one of at least three entrants, along with Medtronic, Inc. and Abbott Laboratories, likely to enter the U.S. market by the end of 2007. Guidant is the only anticipated entrant with rights to the intellectual property necessary to market a DES with the RX delivery system, the dominant delivery system in the United States.

Developing and receiving FDA approval for a DES is difficult, time-consuming and expensive. It can take hundreds of millions of dollars of research and development, significant funding for clinical trials, and an extensive amount of time to even reach the stage of seeking FDA approval. The regulatory process itself can also be time-consuming as the FDA reviews the volumes of materials and data a company submits in support of its application for approval.

Analysis

Considering all these factors, entry into the manufacture and sale of DESs is impossible to achieve within two to three years.

In addition to the regulatory barriers facing firms seeking to enter the DES market, there are substantial intellectual property barriers an entrant must overcome. Firms must invent around or obtain licenses to patents covering nearly every aspect of a DES, including the design of stents, stent delivery systems, and the drugs and polymers used on DESs. Due to the difficulty of entry, firms must commit to entering the market years in advance of any anticipated entry, and timely and sufficient entry in response to a small but significant price increase is impossible.

The proposed acquisition would cause significant competitive harm in the market for DESs by eliminating Guidant as the only potential competitor with the ability to offer a DES on an RX delivery system. As a third RX entrant into the DES market, Guidant likely would increase competition and reduce prices for DESs. Although two other firms, Abbott and Medtronic, are poised to enter the market in the same approximate time frame as Guidant, their lack of access to the RX delivery system makes it unlikely that either company could be a substantial competitive constraint on the DES market in the near term. The proposed acquisition therefore decreases the number of potential DES suppliers with access to the RX delivery system from three to two until at least late 2008, when Guidant's key patents relating to the RX delivery system begin to expire. (The relevant Boston Scientific RX patents begin to expire this year).

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in the market for DESs. Pursuant to the proposed Consent Agreement, the combined J&J/Guidant is required to license Guidant's intellectual property surrounding the RX delivery system at no minimum price to an up-front buyer with a DES program in development no later than ten (10) days after the acquisition is consummated. Through the course of the investigation, Commission staff gathered a great deal of information about each

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of the companies developing DES products. In particular, staff investigated potential divestiture candidates and concluded that Abbott was among the companies well-positioned to replicate the competitive impact Guidant was likely to have absent the proposed acquisition. The parties have selected Abbott as the up-front buyer for the divestiture package. Abbott is a well-known and respected pharmaceutical and diagnostics company that has a number of vascular devices on the market already or in development. It has experience with both drugs and vascular devices, a highly regarded DES design, a strong and growing vascular sales force, and the necessary manufacturing capabilities. Abbott, therefore, is poised to become a strong competitor in the DES market when it enters in the second half of 2007, approximately the same time as Guidant's anticipated date of entry. Access to the RX delivery system will allow Abbott to replace Guidant as the third entrant into the DES market with an RX delivery system.

The Commission's merger remedies are intended to maintain or to restore the competitive *status quo*. The Commission does not, as a matter of course, seek to "improve" on pre-transaction competition. Based on the evidence gathered in the investigation, the Commission has determined that the license to Abbott should replicate the competitive conditions in DESs that existed prior to the proposed transaction between J&J and Guidant. As a result, a Commission order requiring licenses to additional parties is not necessary.

Given the uncertainty inherent in a development program, the RX license contemplated by the proposed Consent Agreement is transferable, so that if Abbott's DES program is not successful, it will have the incentive and ability to transfer the RX license to another firm developing a DES, ensuring that a successful third DES firm is able to enter the market with an RX delivery system in the relevant timeframe. The proposed Consent Agreement also requires the parties to enter into a covenant not to sue Abbott in relation to certain intellectual property rights regarding stent design, stent coating and the use of certain drugs on a stent.

Analysis

Endoscopic Vessel Harvesting Devices

EVH devices are used in coronary artery bypass graft (“CABG”) surgery to remove a patient’s leg vein, arm artery, or other blood vessel that is then used as a conduit to bypass one or more blocked coronary arteries. EVH devices allow for a minimally-invasive procedure requiring only one to three small incisions. EVH has several clinical benefits over the other methods of vessel harvesting (the open method and bridging) both of which are much more invasive, leave large, unsightly scars and carry a greater risk of infection. Surgeons and physician’s assistants would not switch to these other methods of vessel harvesting even if the price of using EVH devices increased by five to ten percent.

As with DESs, the United States is the relevant geographic market in which to analyze the effects of the proposed acquisition on the EVH device market. EVH devices are also medical devices subject to regulation by the FDA. Receiving FDA approval to market an EVH device in the United States can be a lengthy process, but is necessary in order to sell the devices in the United States. EVH devices sold outside of the United States but not approved by the FDA for sale in the United States therefore do not provide viable competitive alternatives for U.S. consumers.

The U.S. market for EVH devices is highly concentrated with J&J and Guidant as the only competitors until very recently, when Terumo Corporation entered. Guidant currently dominates the market with over eighty percent market share. Terumo received FDA approval for its device in January, 2005 and has yet to generate significant sales.

Firms seeking to enter the market for EVH devices face regulatory hurdles and significant intellectual property barriers, both of which make entry into the market for EVH devices in the next two to three years highly unlikely. In addition, while the use of EVH devices in CABG surgery is increasing, the number of overall CABG surgeries appears to be decreasing due to, among

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other things, the increase in stenting procedures; this steady decline in the number of CABG procedures being performed in the United States makes it less likely that firms would choose to enter the EVH device market in response to a modest increase in the price of the devices.

The proposed acquisition would constitute a virtual merger to monopoly in the market for EVH devices and is likely to lead to increased prices and decreased innovation in the market for those devices. Until recently, Guidant and J&J were the only two firms to offer an EVH device in the United States, and while Terumo recently entered, it is likely that it will take several years before Terumo's device has a significant impact on the market for EVH devices.

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in the market for EVH devices by requiring J&J to divest its EVH product line to a Commission-approved buyer at no minimum price. J&J has reached an agreement to divest the EVH business to Datascope. Datascope, a diversified medical device company, has a line of products used in cardiac surgery, including products used in CABG procedures. Pursuant to the Consent Agreement, J&J is required to accomplish the divestiture of its EVH product line no later than fifteen (15) business days after the acquisition is consummated.

The proposed Consent Agreement permits the Commission-approved buyer of the EVH product line assets to enter into a supply agreement with J&J for a period of up to two (2) years. The supply agreement may be necessary because of the need to recreate or move manufacturing and/or packaging equipment and to allow time for the acquirer to receive approval from the FDA to begin manufacturing and/or packaging EVH device kits in its own facility. This supply agreement may also be necessary to allow J&J to supply certain components of the EVH devices until the acquirer is able to procure similar components from third-party vendors.

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In addition, the proposed Consent Agreement permits J&J to provide certain transitional services to the Commission-approved buyer of the EVH product line assets. These transitional services may be necessary for a smooth transition of the product line to the acquirer and to ensure continued and uninterrupted service to customers during the transition.

Proximal Anastomotic Assist Devices

Surgeons use proximal AADs in CABG procedures to avoid the need to clamp the aorta when attaching a harvested vessel to it. If a proximal AAD is not used, the surgeon must use a clamp to stop the flow of blood to a segment of the aorta while the harvested vessel is surgically attached. Using a clamp can cause calcified plaque particles to dislodge from the aorta and travel through the blood stream to the brain, risking neurological dysfunction or stroke.

The proper geographic market in which to analyze the effects of the proposed transaction on the market for proximal AADs is the United States. Proximal AADs are medical devices that must be approved by the FDA before being marketed in the United States. As with other medical devices, the clinical testing and regulatory approval process for proximal AADs can be costly and time-consuming, preventing proximal AADs approved outside of the United States but not approved within the United States from serving as a competitive alternative for U.S. consumers.

There are currently three firms in the U.S. market for proximal AADs, making it a highly concentrated market. The evidence indicates that J&J and Guidant's manual proximal AADs are each others' closest competitors. Medtronic also participates in the market with an automatic device that it recently launched in the United States. A fourth firm, St. Jude Medical, removed its automatic device, Symmetry®, from the market last year amidst reports of device failures. J&J's proximal AAD, eNclose®, was

Analysis

developed and is manufactured by Novare; J&J and Novare have a distribution agreement making J&J the sole distributor of eNclose® in the United States.

As with the other medical devices discussed, entry into the market for proximal AADs is difficult, costly, and time-consuming. Additionally, the alleged safety concerns regarding St. Jude's Symmetry device have resulted in greater scrutiny of proximal AADs by the FDA. The increased scrutiny is likely to substantially increase the cost of developing a proximal AAD. In addition, it appears that the publicity surrounding Symmetry's removal from the market has dampened physician enthusiasm for these devices. These developments, along with the declining number of overall U.S. CABG procedures, decrease the likelihood of entry into this market.

The proposed acquisition is likely to cause significant competitive harm in the market for proximal AADs by eliminating competition between J&J and Guidant and reducing the number of competitors in the market from three to two. The evidence has also shown that J&J and Guidant's products are likely each others' closest competitors in the proximal AAD market because they are more similar to each other than to Medtronic's product. The proposed acquisition is therefore likely to enable the combined J&J/Guidant to raise prices for proximal AADs unilaterally.

The proposed acquisition's anticompetitive effects in the market for proximal AADs are remedied by the proposed Consent Agreement's requirement that J&J terminate its distribution agreement with Novare for Novare's proximal AAD, eNclose. It is anticipated that it will take Novare no more than two months to find a new distribution partner for eNclose.

Appointment of an Interim Monitor and a Divestiture Trustee

The proposed Consent Agreement contains a provision that allows the Commission to appoint an interim monitor to oversee

Analysis

J&J's compliance with all of its obligations and performance of its responsibilities pursuant to the Commission's Decision and Order. The interim monitor is required to file periodic reports with the Commission to ensure that the Commission remains informed about the status of the divestitures, about the efforts being made to accomplish the divestitures, and the provision of services and assistance during the transition period for the EVH divestiture.

Finally, the proposed Consent Agreement contains provisions that allow the Commission to appoint a divestiture trustee if any or all of the above remedies are not accomplished within the time frames required by the Consent Agreement. The divestiture trustee may be appointed to accomplish any and all of the remedies required by the proposed Consent Agreement that have not yet been fulfilled upon expiration of the time period allotted for each.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order or to modify its terms in any way.

Order

IN THE MATTER OF

ENTERGY CORPORATION

ORDER REOPENING AND SETTING ASIDE ORDER

On March 3, 2005, Entergy Corporation (“Entergy”) and Entergy-Koch, LP (“EKLP”), respondents named in the consent order issued by the Commission on January 31, 2001, in Docket No. C-3998 (“Order”), filed their Petition of Entergy and EKLP to Reopen and Set Aside Order in this matter (“Petition”). Entergy and EKLP ask the Commission to reopen and modify the Order in its entirety pursuant to Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. § 45(b), and Section 2.51 of the Commission’s Rules of Practice and Procedure, 16 C.F.R. § 2.51, thereby relieving them of Entergy’s and EKLP’s reporting and posting obligations, which comprise the only ongoing performance obligations under the Order and which otherwise will continue until January 31, 2007. Respondents contend, inter alia, that significant changed circumstances eliminate the continuing need for the Order’s requirements. Petition at 2, 8-9. The Petition was placed on the public record for thirty days pursuant to Section 2.51(c) of the Commission’s Rules. No comments were received. For the reasons stated below, the Commission has determined to grant the Petition.

The Complaint issued with the Order in Docket No. C-3998 states that, on May 26, 2000, Entergy and Koch Industries, Inc. (“Koch”) entered into an agreement to form EKLP, a limited partnership owned equally by Entergy and Koch, and that each contributed certain assets to EKLP. (Complaint ¶ 12). Among other things, EKLP acquired Gulf South Pipeline Company LP (“Gulf South”), a major supplier of natural gas pipeline transportation in Louisiana and Mississippi, from Koch (Complaint ¶¶ 6, 12, 19). Entergy, in turn, acquired a fifty percent interest in Gulf South through EKLP, including the right to fifty percent of EKLP’s profits. (Complaint ¶ 10). At the same time, Entergy also owns regulated utilities that supply electricity to